Remarks/Arguments

Claims 1-15, 17-26 and 28-30 are pending.

112 Rejection

Claims 1-15, 17-26 and 28-30 are objected to under 35 U.S.C. 112, second paragraph, as being indefinite. The applicant respectfully disagrees for at least the following reasons.

Data used in fitting

The Examiner contends that in claims 1 and 21 it is unclear what data is used for calculating the deviates and sum of weighted deviates.

Claim 1 and 21 each recites:

"calculating for each of said sets, a deviate of a predicted risk from <u>an indicator of disease status</u> for that set, said predicted risk predicted <u>using said candidate model</u> and <u>non-genetic data in that set</u>" (emphasis added).

From the above, it is clear that for each data set, a predicted risk is calculated using the candidate model and <u>non-genetic data</u>, and a deviate is calculated using the predicted risk and the <u>indicator of disease status</u>. It is therefore clear that <u>non-genetic data</u> and the <u>indicator of disease status</u> in that data set are used in the calculation of the deviate.

Claim 1 and 21 also each recites:

"calculating a sum of weighted deviates for all of said sets, wherein each deviate is weighted in said sum by a weight associated with, and indicating a statistical significance of, that set for which said each deviate has been calculated, and determining the weights used to weight said deviates with a constraint that said weights associated with sets of said data having like <u>genetic data</u> are the same"

(emphasis added).

From the above, it is clear that <u>genetic data</u> is used in the calculation of the sum of weighted deviates, as the recited <u>constraint</u> necessarily requires comparison (i.e. use) of the <u>genetic data</u> for different data sets.

In summary, it is rather clear that non-genetic data, genetic data, and indicators of disease status are all used in the "fitting" as recited in claims 1 and 21.

<u>Constraint</u>

The Examiner also contends that the "constraint" recited in claims 1 and 21 is unclear as the following two interpretations are possible: (i) the constraint is that the weights are the same, and (ii) the constraint is that weights are restricted to a subpopulation of the genetic data in which the genetic data is restricted to be the same.

Claim 1 and 21 each recites:

> "determining the weights used to weight said deviates with a <u>constraint</u> <u>that</u> said weights associated with sets of said data having like genetic data are the same"

> (emphasis added).

Applicants respectfully submit that interpretation (ii) proposed by the Examiner is not a proper interpretation of the above text, if correct English grammar is followed for understanding the above quoted text. Specifically, the word "that" following the word "constraint" indicates that what follows is a sentence clause requiring a <u>subject</u> and a corresponding <u>verb</u>. The only possible subject in the sentence clause is "said weights", which immediately follows the word "that". The only word of the proper form for a verb in the clause sentence is "are". Thus, the only proper interpretation is that the weights [...] are the same.

The interpretation (ii) suggested by the Examiner might be possible if the word "associated" or "having" was the verb for the subject "said weights". However, if so, the word "associated" or "having" would not be in the correct tense in the context, and there would be two verbs (both "associated" or

"having" and "are") in a single sentence, which would be grammatically incorrect.

The Examiner further suggests that the recited constraint is inconsistent with the description. However, the description states the following:

(1) The data sets are grouped "so that the genetic data 110 of the data sets 104 in each group 506 share some common features" (see para. [0062]).

(2) "A group weight [...] is determined for a group" (see para. [0076]), and "The corresponding weight 114 of <u>each</u> data set 104 within a group 506 <u>equals</u> the <u>group weight</u> 510 for that group 506" (see para. [0082]) [emphasis added].

Thus, the exemplary procedure described in paragraphs [0062] to [0082] ensures that from (1), the data sets in each group have <u>like</u> genetic data, and from (2), the weights associated with the data sets in a group <u>are the same</u>. This exemplary procedure is thus consistent with the recitation in claims 1 and 21.

<u>"reflecting genetic data"</u>

The Examiner also objects to claim 28 and contends that it is not clear what is meant by a weight "<u>reflecting genetic data</u>". The Examiner asks for clarification as to whether this phrase indicates that the weight is determined from the genetic data, or this phrase is an intended use of the weights. Applicants respectfully submit that the phrase is clear on its face as it is a simple statement of the current state of the weights – each weight reflects the corresponding genetic data. As such, it is clear if any given weight meets this recitation or not, regardless of how the weight is determined or what the intended use of the weight is. If the Examiner considers that this phrase is possibly stating an intended use due to the presence of the word "for" appears in the modifier "for whom that deviate is calculated", it is noted that it should

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be clear that the expression "for <u>whom</u>" modifies "that member", not the "weight". Further, it should be clear that the word "for" in "for whom" does not indicate any intended use. It is also noted that claim 28 is a method claim and the recited weight <u>is used</u> in the method to reflect the genetic data, as recited. Thus, it is submitted that it is not necessary to amend the claims to further clarify how the weights are determined, or the intended use of the weights.

In view of the above, withdrawal of the rejection to claims 1-15, 17-26, and 28-30 under 35 U.S.C. 112, second paragraph, is respectfully requested.

<u>103 Rejection</u>

As an initial matter, it is noted that the Examiner states in the Office Action that claims 1-15 and 17-26 are examined based on the interpretation that only non-genetic data are used in the calculation of deviates and weighted deviates as recited in claims 1 and 21. However, as discussed above, this interpretation is incorrect, and non-genetic data, genetic data, and indicators of disease status are all used in the "fitting" as recited in claims 1 and 21, and claims dependent therefrom.

The Examiner's rejections to the claims in view of the cited art should be withdrawn for at least this reason alone, as the Examiner has failed to consider all of the features recited in the claims when assessing whether the claims are patentable over the cited art.

Specifically, the Examiner rejects claims 1-3, 9, 13-15, 17-21, and 28-30 under 35 U.S.C. 103(a) as obvious having regard to Walter et al. in view of Pharaoh et al., Shattuck-Eidens et al., and Pfeffermann et al. The Examiner also rejects claims 4-5, and 23-26 under 35 U.S.C. 103(a) as obvious having regard to Walter et al. in view of Pharaoh et al., Shattuck-Eidens et al., and Pfeffermann et al., as applied to claims 1-3, 9, 13-15, 17-21, and 28-30, and further in view of Nelson et al. and Marshal et al. The Examiner further rejects claims 6-11 under 35 U.S.C. 103(a) as obvious having regard to Walter et al. in view of Pharaoh et al., Shattuck-Eidens et al., Pfeffermann et al., Nelson et

al., and Marshal et al., as applied to claims 1-3, 9, 13-15, 17-21, and 28-30, and further in view of Parzen et al.

The Examiner admits that Walter et al. does not disclose calculation of a sum of weighted deviates for data sets under the constraint recited in claims 1 and 21. However, the Examiner contends that it would have been obvious to modify Walter et al. according to Pharaoh et al., and Shattuck-Eidens et al. to arrive at this feature.

However, the Examiner has failed to point out where in the cited art there is disclosed or suggested the "fitting" features recited in present claims 1 and 21, particularly the calculation of <u>the deviate</u> and the <u>sum of weighted deviates</u> as discussed above.

The Examiner considers the optimization procedure disclosed in Shattuck-Eidens et al. as disclosure of "fitting model parameters by calculating a sum of weighted deviance of a predicted risk using <u>non-genetic data</u>" (p. 8 of the Office Action, emphasis added).

In contrast, and as discussed above, calculation of the sum of weighted deviates as recited in claims 1 and 21 requires the use of <u>genetic data</u>, although non-genetic data and the indicator of disease status are used in the calculation of the deviates.

Careful review of the cited references reveals that there is no disclosure or suggestion in any of the cited references, ether alone or in combination, that the sum of weighted deviates should be calculated using <u>genetic data</u> in the manner as recited in claims 1 and 21, when non-genetic data and the indicator of disease status are used in the calculation of the deviates. In particular, the cited references, either alone or in combination, fail to disclose or suggest determining the weights with a "constraint" as recited in claims 1 and 21 and discussed above. (It is also noted that the Examiner appears to have construed the "constraint" feature based on interpretation (ii) discussed above, which is incorrect.)

Therefore, the Examiner has failed to establish a *prima facie* case of obviousness regarding claims 1-15 and 17-26, and withdrawal of the rejections of these claims is respectfully requested.

The Examiner has not provided any specific and separate grounds for the rejection of claims 28-30 in view of the cited references. To the extent that claims 28-30 were rejected on the same grounds as claims 1 and 21, it is believed that the rejections have been addressed for at least the same reasons discussed above, and withdrawal of the rejections of claims 28-30 is respectfully requested.

In view of the foregoing, favorable reconsideration and allowance of the application is respectfully requested.

Respectfully submitted,

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